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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/675,509	FULTON ET AL.	
	Examiner	Art Unit	
	Thaian N. Ton	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The finality of the final Office action, mailed 1/25/06, is withdrawn. Applicants' After-Final amendment, filed 7/19/06, is entered. Claim 10 is pending and under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a eukaryotic expression vector comprising a recombinant nucleic acid sequence encoding thiaminase I of SEQ ID NO: 3, does not reasonably provide enablement for the breadth of the claims, a eukaryotic expression vector comprising any recombinant nucleic acid sequence encoding thaiminase I from *N. gruberi*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

The claim is directed to eukaryotic expression vector comprising a recombinant nucleic acid sequence encoding thiaminase I from *N. gruberi*.

The specification teaches SEQ ID NO: 3, which encodes thiaminase I from *N gruberi*. However, the specification does not teach how to make and use the recombinant sequences that are encompassed by the breadth of the claims. Given the broadest reasonable interpretation, claim 10 encompasses any recombinant nucleic acid sequence that encodes thiaminase I from *N. gruberi* and that such sequences could be isolated from any source. The specification does not teach how to make and use any recombinant nucleic acid isolated from any source, such that it would encode thiaminase I of *N. gruberi*. The instant specification further teaches that thiaminases can be encoded by full-length nucleic acid sequences, or portions of these sequences. Furthermore, these sequences comprise naturally- occurring sequences or functional derivatives. See page 9, lines 3-10, of the specification, for example. Thus, the claims encompass sequences that are not derived from *N. gruberi* that encode thiamianse I, because the term "recombinant" encompasses sequences from other species, or any derivatives thereof. Furthermore, the claims encompass portions or fragments of sequences that encode thiaminase I from *N. gruberi*, wherein these sequences are not enabled by the instant specification. The specification does not teach how to use a non-functional or non-active enzyme, or a nucleic acid sequence that encodes the same.

The specification does not teach how to make fragments or variants that would retain the activity of thiaminase I of *N. gruberi*. In particular, the skilled artisan would not know what parts of SEQ ID NO: 3 to delete, or modify, such that the resultant fragment would have the activity of the wild-type protein. Furthermore, Applicants do not teach the structure of variants of SEQ ID NO: 3 that would encode a protein that would have the activity of thiaminase I of *N. gruberi*.

Additionally, claims are directed to a nucleic acid sequence that encodes thiaminase I from *N. gruberi*, however, there is no specific recitation that upon

expression of the vector, an active thiaminase enzyme would be produced. Thus, the claims encompass sequences that encode non-functional or non-active enzymes.

Accordingly, in view of the lack of teaching or guidance provided by the specification with regard to recombinant nucleic acid sequences that encode thiaminase I from *N. gruberi*, other than SEQ ID NO: 3, as well as the lack of teaching with regard to sequences that encode an active thiaminase I from *N. gruberi*, other than that which is encoded by SEQ ID NO: 3, it would have required undue experimentation for one of skill in the art make and use the claimed invention, as broadly claimed.

Written Description

Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that, "[A]pplicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar,* 19USPQ2d at 1117. The specification does not, "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

While the specification provides adequate written description for a eukaryotic expression vector comprising a recombinant nucleic acid sequence encoding thaiminase I of SEQ ID NO: 3, it does not provide sufficient guidance with regard to other recombinant nucleic acid sequences that encode thiaminase I from *N. gruberi*. The specification teaches that thiaminases can be encoded by full-length nucleic

acid sequences, or portions of these sequences. Furthermore, these sequences comprise naturally-occurring sequences or functional derivatives. See page 9, lines 3-10, for example. Thus, the claims encompass recombinant nucleic acids, which are functional derivatives or could have portions of sequences from other organisms, that encode thiaminase I of *N. gruberi*. While the specification teaches that SEQ ID NO: 3 as encoding thiaminase I from *N. gruberi*, there is no description of other recombinant nucleic acids that would encode thiaminase I from *N. gruberi*, as instantly claimed. The skilled artisan could not envision the detailed chemical structure of the eukaryotic expression vectors that would be representative of the encompassed recombinant nucleic acid sequences encoding thiaminase I from *N. gruberi*. Additionally, the specification does not describe what would be the core structure of the claimed recombinant nucleic acids that could be used as further distinguishing characteristics of the members of the claimed genus. Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than it is part of the invention, and a reference to a potential method of isolating it. Thus, the instant invention does not meet the written description requirement in that the specification does not provide a description of the invention, with all its limitations, as stated in MPEP §2163.

See *Fiers v. Revel,* 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification only provided the bovine sequence.

Applicant is reminded that *Vas-Cath* makes clear that the written description of 35 U.S.C. 112 is severable from its enablement provision [see p. 1115].

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Ram Shukla, SPE of Art Unit 1632, at (571) 272-0735. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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